HEALTH OCCUPATIONS

PHYSICIANS — APPLICATION OF LAWS ON FEE-SPLITTING KICKBACKS, AND SELF-REFERRALS

May 26, 1998

The Honorable Paula Colodny Hollinger Maryland Senate

You have asked for our opinion concerning the application of four separate federal and State laws that attempt to avert conflicts of interest in medical practice. These laws are the Maryland feesplitting statute, the federal anti-kickback statute, the federal self-referral statute, and the Maryland self-referral statute. Specifically, you have asked how these laws might apply to a situation involving the purchase of a group practice by an entity partly owned by an affiliate of a hospital, and to subsequent arrangements concerning delivery of services by that practice.

We must begin with an explicit acknowledgment of the limits of this opinion. In general, we will decline to state firm conclusions. Our reticence derives from several factors: the highly uncertain state of the law; the necessity to write an opinion based on a set of complicated facts as given, when additional facts might change the analysis; our inability to make judgments about financial matters, like the "fair market value" of certain services, that are inextricably linked to legal conclusions; and, finally, the reality that abstract conclusions in an opinion cannot substitute for the judgment of those who enforce these laws in particular cases, who are able to develop a fuller factual record, and who therefore may have a different perspective on the situation than we do.

Your request presents complex issues that are on the cutting edge of the business side of health care. These issues require the interpretation of statutes about which there is little guiding case law. Furthermore, regulations to implement these provisions are not fully in place, and are constantly being reviewed and revised. See Acosta, The Health Insurance Portability and Accountability Act of 1996 and the Evolution of the Government's Anti-Fraud and Abuse

Agenda, 30 J. Health & Hosp. Law 37 (1997); Dechene, "Stark II" and State Self-Referral Restrictions, 29 J. Health & Hosp. Law 65 (1996). As a result, the law dealing with joint ventures, kickbacks, and payments for referral has been said to be an "area in which darkness and chaos reign." Hennigan, Structuring Ventures in a Post-Hanlester and Safe Harbors World, 14 Whittier L. Rev. 181, 182 (1993).

In addition, an investigation of whether these laws have been violated is a complex and painstaking matter. Each transaction must be analyzed in minute detail. Your request, by necessity, contains but a brief overview of the facts. Although we have attempted to supplement the facts through inquiries to the person whose situation prompted your request, opinion writing is not an investigatory process. Neither you nor we have a full picture of potentially relevant facts. Even if we did, when the facts must be evaluated against broad criteria like commercial reasonableness or fair market value, we lack the expertise to make these sorts of judgments. Yet, it is exactly these judgments that must sometimes be made before a firm legal conclusion can be reached.

For all of these reasons, our answers to the questions that you raise cannot be definitive. Indeed, because our answers are so contingent on the facts, we will depart from our customary practice and not attempt a summary here. Instead, our tentative conclusions will be set out following the discussion of each law and its potential impact on the arrangements in question.

I

Background

A. Factual Narrative

The facts, as we have been given them, concern a group of specialty care physicians, each of whom at some point signed an

We note that, under the federal anti-kickback statute, advisory opinions on certain matters may be sought from the Secretary of Health and Human Services. 42 U.S.C. §1320a-7d(b)(2). "Each advisory opinion issued by the Secretary shall be binding as to the Secretary and the party or parties requesting the opinion." 42 U.S.C. §1320a-7d(b)(4)(A).

employment agreement with a professional medical corporation owned by four primary care physicians. This agreement governed services provided at the location of the professional medical corporation and any consequent hospital services. Under the terms of the agreement, which is renewable from year to year for up to ten years, the compensation of the specialty care physicians includes net collections of fees for services provided and net co-payments made by those patients participating in managed care or insurance plans. The fees are standard fee-for-service or, for patients in health maintenance organizations, a discounted fee-for-service. The specialty care physicians do not get paid on a capitated basis.

The payments are collected by the professional medical corporation, which deducts a 35% fee for overhead. The amount of this deduction is subject to review and adjustment on a quarterly basis but has apparently remained relatively stable over time. This stability has been maintained even though, according to representatives of the managed care company that purchased the professional medical corporation, actual costs for overhead have approached 55%. An additional deduction of 10% is withheld for a "Reimbursement Adjustment Reserve Fund." This fund is subject to reduction based on a number of factors, and the amount remaining is to be paid to the physicians within 90 days of the end of the calendar year. In practice, however, no payouts have been made from this fund. The four primary care physicians who owned the stock of the professional medical corporation entered into the same contract, but also receive net capitation payments, less the overhead fee and reserve fund, as part of their compensation.

In the beginning of 1996, the professional medical corporation was purchased by a local hospital through its corporate affiliate. This purchase apparently included the practices of the primary care physicians and the specialty care physicians, as well as the stock of an affiliated medical services organization, which was owned by two of the primary care physicians. The purchase price was based on an appraisal by an outside consultant of a value "proportional to the revenue historically generated by each of the primary care physicians and specialty care physicians" at the professional medical corporation over a set period of time. The value of the practice of three of the physicians at a retirement care facility was also included. The purchase price was paid to the four primary care physicians who had held the stock of the professional medical corporation. The

hospital liquidated the assets and stock of the corporation and distributed it to the managed care company, which is 49% owned by the hospital and 51% owned by individual physicians. The primary care physicians remained in place and have continued the practice under the terms of the agreement as modified by the terms of the sale and subsequent arrangements with the managed care company. With the addition of these physicians, the managed care company had 23 primary care physicians at eleven locations and intended to expand to include 100 primary care physicians located throughout central Maryland.

After the purchase, the managed care company announced that it would continue the existing employment contracts, with changes in terminology to reflect the new ownership. Subsequently, it has announced that it views the agreement as covering not only the patients who are treated at the old professional medical corporation location (and resulting hospital services for those patients) but also any patient who was referred to a specialty care physician from any physician employed by the managed care company—that is, not only patients referred by the four primary care physicians in the original professional medical corporation but also those referred by physicians who were already, or have since become, a part of the managed care company. In some cases, this group includes patients whom the specialty care physicians have been treating at a retirement care facility prior to their association with the professional medical corporation.

This expansion of the group of covered patients leads to a disparity in the expenses incurred by the managed care company on behalf of the patients covered by the agreement. For example, in some cases, the patients come to the location of the old professional medical corporation to see a primary care physician and are referred to a specialty care physician to be seen at that location. In that instance, the office space, equipment, scheduling, and maintenance of the patients' records are all provided by the managed care company at that site, although there might be an extra charge to the specialty care physician for secretarial services. In another possible situation, a primary care physician employed by the managed care company could refer a patient who was initially seen at the location of the old professional medical corporation to the specialty care physician in the specialty care physician's independent practice. In that case, some of the services mentioned above would come from

the independent practice, not from the managed care company, although record maintenance, billing, and even scheduling might be done by the managed care company. On the other hand, a patient from the retirement care facility that is referred to the specialty care physician and treated at the hospital might not benefit from services provided by the managed care company at all.

In March 1996, the managed care company entered into a participation agreement with a physician-hospital organization ("PHO") that is 50% owned by the hospital and 50% owned by hospital-credentialed participating physicians. The goal of the PHO is to provide services under third-party payor agreements, using provider panels made up of PHO members. Under the agreement with the managed care company, the PHO agrees to negotiate thirdparty contracts on behalf of its members, for which the managed care company pays a fee. The agreement further provides that the managed care company and the physicians in the PHO will accept as patients all enrollees under third-party payor plans who request the services of the managed care company or any of the physicians in the PHO. Members of the PHO include not only physicians from the managed care company but also other physicians, who are not subject to the managed care company contract. Only physicians that meet the qualifications for membership in the PHO may become members; not all physicians within the managed care company qualify. The specialty care physicians who sign the participation agreement pay an additional 7% in administrative fees to the PHO on top of the 45% of fees currently paid to the managed care company for patients in the PHO. The primary care physicians in the managed care company do not sign the participation agreement itself, but are members of an independent practice association, which in turn is a member of the PHO. PHO patients are to be seen only by physicians who are members of the PHO or of the independent practice association, which is a member. While outside referrals are possible, they must be made, or approved by, the medical director of the PHO. The agreement does not currently prevent member physicians from taking patients from outside the PHO.

The medical director of the PHO is a specialty care physician who has an agreement with the managed care company. This agreement is believed to be the same as the one signed by the other specialty care physicians, except that this agreement is believed to include extra compensation for services rendered as the medical

director; the extent and manner of the compensation are not known. All referrals of PHO patients at the hospital must go through the medical director, whether they are to member physicians or to physicians outside the PHO. Thus, the medical director can direct patients to the specialty care physicians that have agreements with the managed care company, with the result that the managed care company will get 45% of the fees earned by the specialty care physicians.

B. Aspects of the Arrangement in Question

You have identified three particular aspects of this arrangement and asked about their legality: the purchase and subsequent transfer of the professional medical corporation, the percentage payment by the speciality care physicians to the managed care company, and the dual employment of the medical director of the PHO.

1. Purchase and transfer.

The first situation that you have asked this office to evaluate is the purchase of the professional medical corporation by an affiliate of the hospital and the subsequent transfer to the managed care company. Specifically, you ask about the payment to the primary care physicians who owned the practice based upon the "anticipated stream of revenue to be received by the managed care company from referrals of patients at the retirement center."

While your letter reflects that, in one instance, the medical director at the retirement care facility was told by the managed care company that the purchase price paid by the managed care company had included "the anticipated revenue stream from their practice," the facts supplied elsewhere indicate that the price of the professional medical corporation was based not on the value of future referrals but rather on the amount of income taken in by the professional medical corporation for treatment of all of the patients seen by physicians under contract with the professional medical corporation over a set period in the past. This method of valuing the business is not unusual, but that fact does not imply that the method is without problems under the various laws regulating self-referral and kickbacks.

2. Percentage payment.

The second situation that you have asked us to evaluate is the payment of a percentage of fees by the specialty care physicians to the managed care company. This fee is 35% plus 10% for an incentive fund that is, as we understand the facts, never returned to the physicians. You have informed us that, in the ordinary case, the managed care company collects fees from the patients or third-party payors and distributes them to the specialty care physicians after deducting the 45%. In that situation, the role of the managed care company is that of a conduit for fees paid by the patients and others, rather than as the payor of the fees.

3. Dual employment.

Finally, you have asked us to evaluate whether any of the laws in question are violated by the dual employment status of the medical director of the PHO, who is also under contract with the managed care company.

We shall refer to each of these circumstances in our analysis of the four statutes about which you asked.

II

Maryland Fee-Splitting Statute

A. Text, History, and Purpose

Under §14-404(a)(15) of the Health Occupations ("HO") Article, Maryland Code, a physician is subject to discipline if the physician "[p]ays or agrees to pay any sum to any person for bringing or referring a patient or accepts or agrees to accept any sum from any person for bringing or referring a patient." This prohibition was originally added to the physician licensing law as part of the 1968 Legislative Policy Committee bill that created a separate disciplinary board for physicians. That bill, enacted as Chapter 469 of the Laws of Maryland 1968, provided that a physician was subject to discipline for "division of fees or agreeing to split or divide the fees received for professional services with any person for bringing to or referring a patient." The 1981 Code Revision bill that created the Health Occupations Article changed the language to subject to discipline a physician who "pays or agrees

to pay any sum for bringing or referring a patient," but the Revisor's Note reflects that this rewording did not effect a substantive change. Chapter 8, Laws of Maryland 1981. The current language reflects an amendment from 1986 that also barred the acceptance of compensation for making a referral. Chapter 26, Laws of Maryland 1986.

The justification for fee-splitting prohibitions is that they prevent a conflict of interest: Fee-splitting creates a danger that non-professionals might recommend the services of a particular professional out of self-interest and not because of the competence of the professional. Also, a physician who knows that he or she must split his fees with someone else might hesitate to provide needed services, or conversely, might provide unneeded services just because of the need to split fees. *Practice Management Ltd. v. Schwartz*, 628 N.E.2d 656 (III. App. 1993), *app. den.*, 633 N.E.2d 14 (III. 1994). *See also Beck v. American Health Group Int'l*, 260 Cal. Rptr. 237, 243 (Cal. App. 1989).

The provision has not been the basis of much activity in Maryland. There are no reported cases, and the legislative history of the 1986 bill reflects that there had only been two complaints in the previous three years, neither of which had been verified. Research Analysis on House Bill 1637 of 1986.

B. Application to Purchase and Transfer Question.

There are circumstances in which the sale of a practice can amount to fee-splitting. For example, the sale of a practice by one physician or group of physicians to another for a percentage of the income of the practice over the next 20 years has been found to be fee-splitting. Lieberman & Kraff v. Desnick, 614 N.E.2d 279 (III. App.) app. den., 622 N.E.2d 1209 (III. 1993). In the transaction about which you ask, however, the purchasing entity is not a physician or group of physicians, and it does not appear from the facts that any payments not made at the time of sale are based on a percentage of earnings by physicians in the managed care company after the sale. Thus, the fee-splitting statute would not appear to be implicated by the sale of the practice.

C. Application to Percentage Payment Question.

In the absence of cases interpreting the Maryland fee-splitting statute, we turn to out-of-state authority. In considering situations where a physician or practice pays a set percentage of the fees to a separate entity for services, courts have generally concluded that illegal fee-splitting occurs only if the percentage paid is not commensurate with the expenses of the entity in providing the services. Thus, an agreement under which radiologists paid 66% of the fees paid by patients in the hospital radiology facility to the hospital was found not to constitute fee-splitting, where the percentage reflected the expenses of the hospital in providing the facilities. Blank v. Palo Alto-Stanford Hospital Center, 44 Cal. Rptr. 572 (Cal. App. 1965). In another case, however, a 50/50 split with a practice management company was found invalid, although the management company provided some services. Management Ltd. v Schwartz, 628 N.E.2d 656 (Ill. App. 1993), app. den., 633 N.E.2d 14 (Ill. 1994). The Illinois court suggested that payment on a percentage basis would always raise questions and that a percentage as high as 50% was certainly indicative of a problem. In another case, where no services were provided, a 20% payment by a physician to a professional corporation that had gotten an exclusive contract to provide services at a nursing home was found to be "indicative of an illegal and unethical fee-splitting arrangement." Hauptman v. Grand Manor Health Related Facilities, 502 N.Y.S.2d 1012 (App. Div. 1986). Payments for marketing services also have been found to constitute fee-splitting. E&B Marketing Enterprises v. Ryan, 568 N.E.2d 339 (Ill. App. 1991).

Under the facts as we are given them, the managed care company provides services for some of the patients seen by the specialty care physicians, but these services vary, depending upon the source of the patient and where the treatment is provided. Although we do not suggest that a percentage fee must accurately reflect the services provided on a patient-by-patient basis, in our view, the Maryland fee-splitting statute requires that the percentage charged must reasonably reflect the value of the services provided to patients in the aggregate. Moreover, while that aggregate might include some patients on whose behalf no services are provided, inclusion of a large, identifiable group of such patients would, in our view, raise fee-splitting problems.

In this case, the 45% charge seems high, but the facts indicate that it may be below the actual overhead when all patients are considered in the aggregate. Thus, we cannot say that a violation is necessarily occurring, although it might be, depending upon the actual value of the services. In addition, if there is a significant group of patients as to whom the fee is charged but no services are rendered, then a violation might be found.

This analysis depends, in part, on the correctness of the conclusion that the arrangement between the managed care company and the specialty care physicians is one in which the specialty care physicians pay a fee to the managed care company that is deducted by the managed care company in its role as a conduit for the collection of fees paid by patients and third parties. If the fee paid to the specialty care physicians is in fact one paid by the managed care company out of a capitated fee that it receives for a member of a plan that has a contract with the PHO, the result would arguably be different, because the physicians would not be splitting a fee received from patients but would be retaining the full amount paid to them for services.

D. Application to Dual Employment Question

Nothing in the facts available to us indicates that this situation raises fee-splitting issues other than those discussed above.

Ш

The Federal Anti-Kickback Statute

A. Text, History, and Construction

The federal anti-kickback statute, 42 U.S.C. §1320a-7b(b), provides that an individual may not "knowingly or willfully solicit or receive any remuneration" for referring an individual for a service for which payment may be made under a "federal health care program." Thus, the statute covers referrals in Medicare and

² A "federal health care program" is defined as any plan or program that provides health benefits funded in whole or in part by the federal government, as well as any state health care program. 42 U.S.C. §1320a-(continued...)

Medicaid as well as a variety of other programs. While a showing that one of these programs is affected is a jurisdictional prerequisite, these programs are so large that any kickback scheme is likely to be covered. The statute provides certain exceptions to its coverage, including an exception for a "bona fide employment relationship." 42 U.S.C. §1320a-7b(b)(3). In addition, the statute requires the Secretary of Health and Human Services to promulgate "safe harbor" regulations under which certain transactions are defined as outside of the statute. These regulations are not intended to permit acts that would otherwise be prohibited, but to define transactions that are clearly not covered by the law and may be engaged in without concern that the law might be violated.

The federal anti-kickback statute was originally enacted in 1972. Pub. L. No. 92-603, 86 Stat. 1329. In 1977, the statute was broadened and clarified, violation of it was made a felony, and the penalty was increased. Medicare-Medicaid Antifraud and Abuse Amendments Act of 1977, Pub. L. No. 95-142, 91 Stat. 1175. One change was to replace the terms "bribe" and "kickback" with the broader term "remuneration," which includes, but is not limited to, bribes and kickbacks. This change eliminated problems that had arisen when courts interpreted the terms "bribe" and "kickback" narrowly. See United States v. Porter, 591 F.2d 1048, 1053-1054 (5th Cir. 1979). Amendments in 1980 added a specific intent requirement, to address concerns that the law might be applied to someone whose conduct "while improper, was inadvertent." H.R. Rep. No. 96-1167, reprinted in 1980 U.S.C.C.A.N. 5526, 5572. See Omnibus Budget Reconciliation Act of 1980, Pub. L. No. 96-499, 94 Stat. 2599. In 1987, the anti-kickback provisions were united in a single section (42 U.S.C. §1320a-7b), and an administrative remedy was added. Medicare and Medicaid Patient and Program Protection Act of 1987, Pub. L. No. 100-93, 101 Stat. 680. amendments also mandated the creation of safe harbor regulations to "provide an area where people can act in total safety from prosecution under the anti-kickback statute." Kusserow, The Medicare and Medicaid Anti-Kickback Statute and the Safe Harbor Regulations – What's Next?, 2 Health Matrix 49, 54 (1992). Finally, the Federal Health Insurance Portability Act of 1996 ("HIPAA"), Pub. L. No. 104-191, 110 Stat. 1936, extended the provisions of the

7b(f).

² (...continued)

law to all federal health care programs, not just Medicare and state health care programs. HIPAA also added an exception for risk-sharing agreements. The general effective date of HIPAA was January 1, 1997.

The application of this law to joint ventures and other types of self-referral arrangements is not fully settled. The Office of the Inspector General in the Department of Health and Human Services, taking a broad view of the statute's reach, would apply it to many self-referral arrangements. Because the law is often enforced through consent agreements, this view has significant weight for parties structuring such agreements. Acosta, The Health Insurance Portability and Accountability Act of 1996 and the Evolution of the Government's Anti-Fraud and Abuse Agenda, 30 J. Health & Hosp. L. 37 (1997). However, the first self-referral case to be tried under the anti-kickback statute, Hanlester Network v. Shalala, 51 F. 3d 1390 (9th Cir. 1995), gave the statute a more restrictive reading. In Hanlester, the court held that self-referral alone was not a violation. Accord, Baglio v. Baska, 940 F. Supp. 819 (W.D. Pa. 1996). Moreover, the court held, for a violation to be "knowing and wilful," the violator must know of the statutory provision and have a specific intent to violate it.

The first of these holdings is consistent with the stated position of the Inspector General. CCH Medicare and Medicaid Guide ¶37,838, at 19,928 ("The current view of federal authorities is that physician ownership does not, in and of itself, violate the antikickback laws."). The Inspector General, however, has disagreed with Hanlester's interpretation of the "knowing and wilful" requirement. See BNA Medicare Reports No. 15, at 463. So have other courts. United States v. Jain, 93 F.3d 436 (8th Cir. 1996), cert. denied, 117 S. Ct. 2452 (1997); United States v. Neufeld, 908 F. Supp. 491, 496-97 (S.D. Ohio 1995); Medical Development Network v. PRC, 673 So. 2d 565 (Fla. App. 1996). Some of these courts have held that the violator need only intend to commit the act that constitutes a violation. United States v. Neufeld, 908 F. Supp. at 495-97; Medical Development Network v. PRC, 673 So. 2d at 567. The Eighth Circuit, in the Jain case, took a middle view, holding that the defendant must act "unjustifiably and wrongfully" and that good faith would be a defense. 93 F.3d at 440-41.

A court that analyzes a transaction to determine whether the anti-kickback statute has been violated will assess whether the payments at issue were for legitimate services. The mere fact that legitimate services were provided, however, will not protect against a finding of a violation, if part of the purpose was to induce referrals. United States v. Kats, 871 F.2d 105, 108 (9th Cir. 1989); United States v. Greber, 760 F.2d 68 (3rd Cir.), cert. denied, 474 U.S. 988 (1985); United States v. Neufeld, 908 F. Supp. at 497. This is true even if the government cannot prove that the payments received exceeded reasonable value for the actual work done. United States v. Bay State Ambulance & Hosp. Rental Serv., 874 F.2d 20, 29 (1st Cir. 1989). In Hanlester, however, the court drew a distinction between an intent to encourage referrals, and an intent to induce them, holding that only the latter would violate the Act. 51 F.3d at Thus, according to Hanlester, a violation would not established simply by proof that a joint venture was marketed to those that were in a position to make referrals, that a high number of referrals would result in the opportunity for a high return on investment, or that the practical effect of a low referral rate was that the venture would fail. Id.

Courts have interpreted the statute broadly in other ways. The term "remuneration" has been given a broad interpretation and includes the opportunity to make money. *United States v. Bay State Ambulance & Hosp. Rental Serv.*, 874 F.2d at 29; *Polk County v. Peters*, 800 F. Supp. 1451 (E.D. Tex. 1992). Moreover, unilateral intent suffices to violate the statute. In other words, if the payor intended to induce referrals, the absence of an express agreement is immaterial. *Hanlester Network v. Shalala*, 51 F.3d at 1396-97; *Vana v. Vista Hospital Systems*, 1993 WL 597402 (Cal. Super. 1993) (unpublished).

A broad interpretation of this statute, one commentator has suggested, endangers "business arrangements which are encouraged by, and comport with, the present incentives created by Medicare's prospective payment system," because the acknowledged intent of these ventures is to increase the hospitals' revenue streams. Comment, *The Medicare-Medicaid Anti-Fraud and Abuse Amendments: Their Impact on the Present Health Care System*, 36 Emory L. J. 691, 693 (1987). It has also been suggested that the statute might be given a narrower interpretation if the issue were to arise in a case that does not involve a blatant kickback scheme. *Id.*

See also Comment, Curing the Health Care Industry: Government Response to Medicare Fraud and Abuse, 5 J. Contemp. Health Care L. & Policy 175, 183 (Spring 1989) (hereafter cited as Curing the Health Care Industry). The restrictive reading of the court in Hanlester has been praised as an appropriate way to limit the perceived overbreadth of the statute, especially in the area of self-referral. Kucera, Hanlester Network v. Shalala: A Model Approach to the Medicare and Medicaid Kickback Problem, 91 N.W.U. L. Rev. 413, 446-52 (1996).

B. Application to Purchase and Transfer Question

A hospital's purchase of a physician practice raises anti-kickback issues, at least where the physician remains in practice and is in a position to make referrals to the hospital. "The intent of a hospital's participation in a joint venture is to preserve their existing patient base, to obtain a referral stream and to increase their ability to compete with alternative health care delivery systems The intent to increase the hospital's referral stream technically violates the broad prohibition of the Medicare anti-kickback provision.". Curing the Health Care Industry, 5 J. Contemp. Health Care L. & Policy at 198. In fact, it has been suggested that all hospital-physician joint ventures have this aim. Id.

An early letter from the Office of the Inspector General on this issue suggested that payment for intangibles (including goodwill, covenants not to compete, exclusive dealing arrangements, the value of an ongoing business unit, patient lists, and patient records) might be payment for a stream of referrals and, thus, violate the antikickback statute. Letter from D. McCarty Thornton, Associate General Counsel, to T. J. Sullivan, Internal Revenue Service (December 22, 1992). Mr. Thornton also expressed the view that the fair market value of a practice may not include elements of "traditional or common methods of economic valuation," because certain "[i]tems ordinarily considered in determining the fair market value may be expressly barred by the anti-kickback statute." The third major point in the letter was that the Inspector General's concern extends not only to arrangements in which the purchasing entity enters into independent contractor relationships with the physicians after a practice acquisition but also to arrangements in which the purchasing entity and the physicians enter into

employment relationships, notwithstanding the "bona fide employee" exception in the statute.

Since the issuance of the letter, the Office of the Inspector General has retreated somewhat, saying that it does not believe that a hospital can never purchase a physician practice or even that it cannot pay for good will or other items beyond the hard assets of such a practice. See 1 BNA Health Care Policy Report, No. 5, at 216 (April 5, 1993). Nevertheless, the office has continued to express concern that the hospital may really be buying the flow of business from the physicians to the hospitals. Id. The Inspector General has suggested that a solution might be to judge these transactions based upon the amount that a new doctor would pay a retiring doctor for the latter's practice. Id.

Thus, if the question is about the legality of the payment, assuming that the payment was based on an anticipated future stream of referrals from the primary care physicians to the hospital, or to the physicians employed by the managed care company, the question answers itself: the federal anti-kickback statute would be violated. If, however, the facts are that the payment was based on past earnings of the professional medical corporation, the legality of the transaction depends on whether the price paid would be reasonable in a context in which there was no opportunity for referrals.³ We cannot make this determination of reasonableness.

C. Application to Percentage Payment Question

One way that the payments to the managed care company might violate the anti-kickback statute would be if it were shown that they are (i) made with the intent of inducing referrals by the managed care company to the specialty care physicians for services

³ It is clear that the safe harbor for sale of a practice does not apply to this situation, because it applies only when one practitioner is selling a practice to another practitioner and requires that the practitioner who is selling the practice not be in a professional position to make referrals to, or otherwise generate business for, the purchasing practitioner after one year from the date of the first agreement pertaining to the sale. 42 C.F.R. §1001.952(e). Failure to fit within this or another regulatory safe harbor, however, does not necessarily mean that the statute is violated. 63 Fed. Reg. 1662 (January 9, 1998).

that are covered by Medicare, Medicaid, or another federally funded health program; (ii) not the subject of a statutory exemption; and (iii) not covered by a safe harbor regulation. The managed care company appears from the facts to be functioning as a management services organization. Management services organizations typically acquire the assets of one or more independent physician practices and thereafter furnish space, equipment, personnel, and management services to the practices. They might also provide managed care negotiation services. Conn, Trends in the Integrated Delivery of Health Care and the Corporate Practice of Medicine, 9 Health Care Law Newsletter, No. 10 (October 1994). Management services organizations are common in the health care field, and payments to them are not, in themselves, evidence of an intent to induce referrals. Cf. Hanlester v. Shalala, 51 F.3d at 1401 (management services arrangement in clinical laboratory context). As with the fee-splitting law, however, payments to a management services organization must reflect the value of services provided in order to avoid kickback problems. Hastings, Physician-Hospital Integration: Beyond Contracting Models, Health Law Handbook (1995).

Unlike the Maryland fee-splitting law, the federal antikickback law applies to any person who makes payments intended to induce referrals, not just to physicians. Thus, another way that the anti-kickback law could be violated is if the managed care company provides services to the specialty care physicians for less than their cost, with the intent of inducing the physicians to make referrals to other managed care company physicians. Polk County v. Peters, 800 F. Supp. 1451 (E.D. Tex. 1992); Vana v. Vista Hospital Systems, 1993 WL 597402 (Cal. Super. 1993) (unpublished); Note, *Provider* Contract Joint Ventures, Are They Defensible Under the Medicare, Medicaid Anti-Kickback Statute?, Bender's Health Care Law Monthly (August 1996); Comment, The Medicare-Medicaid Anti-Fraud and Abuse Amendments: Their Impact on the Present Health Care System, 36 Emory L. J. 691, 739 (1987). This principle is reflected in the safe harbor regulations that relate to rental of office space and equipment, which require that the rental be consistent with fair market value and not determined in a manner that takes the volume or value of referrals into account. 42 C.F.R. §1001.952(b) and (c).

Finally, the language of the anti-kickback statute does not foreclose the possibility that it would be violated if one party makes

payments in return for referrals that are made to a third party. Thus, a violation could occur if the managed care company performed services for less than their cost in return for referrals by the specialty care physicians to the hospital. Conversely, payments made by the physicians to the managed care company to induce the hospital to make referrals to the specialty care physicians would also be covered. Of course, whether the intent was to induce such referrals would have to be answered on a case-by-case basis, and the proof in cases where referrals to or from a third party is involved would likely be correspondingly more difficult.

Presumably, the imbalance in payment, if any, only goes one way, so that the arrangement could constitute illegal remuneration under the anti-kickback law only in one direction or the other. As we have pointed out, we lack the information that would be necessary to determine the relationship between the fees and the costs of the services provided. If the issue is whether the percentage fee amounts to a kickback from the physicians to the managed care company for referral of patients, it would appear that none of the statutory exemptions or the safe harbors would be applicable. There is a safe harbor for payments that are made pursuant to a personal services contract, but the aggregate compensation must be set in advance and cannot take into account the volume or value of any referrals or business otherwise generated between the parties. 42 C.F.R. §1001.952(d). The percentage fee paid to the managed care company will obviously be of more value as more patients are referred by the member primary care physicians to the specialty care physicians. Thus, this safe harbor would not be available in this situation. See Nursing Home Consultants v. Quantum Health Services, 926 F. Supp. 835 (E.D. Ark. 1996).⁴

⁴ A proposed safe harbor would allow arrangements under which an individual agrees to refer a patient to a practitioner for specialty services in return for an agreement on the part of the specialist to refer that patient back at a certain time or in certain circumstances. 58 Fed. Reg. 49008 (September 21, 1993). However, there may not be any actual payment between the parties unless they are members of the same group practice. As there is, in effect, a payment between the specialty care physicians and the primary care physicians, this safe harbor, even if adopted as a final regulation, would apply only if the practice is determined to be a group practice and that group practice is deemed to include specialists that (continued...)

If the imbalance goes the other way, and the issue is whether it amounts to a payment by the managed care company to the physicians to induce the referral of patients to managed care physicians or to the hospital, it would likewise appear that these payments also would not qualify for any of the arguably applicable exceptions or safe harbors. The statute exempts amounts paid by an employer to an employee who has a bona fide employment relationship with an employer "for employment in the provision of covered items or services." 41 U.S.C. §1320a-7b(b)(3)(B). The contractual relationship between the managed care company and the specialty care physicians, however, is such that, in our view, the physicians should be considered to be independent contractors rather than employees.

Five criteria are generally considered in determining whether a person is an employee or an independent contractor. They are (1) the power to select and hire the employee, (2) the payment of wages, (3) the power to discharge, (4) the power to control the employee's conduct, and (5) whether the work is a part of the regular business of the employer. Mackall v. Zayre Corp., 293 Md. 221, 230, 443 A.2d 98 (1982). Of these, the factor of control is the most important, in that no other factor, standing alone, is controlling. Whitehead v. Safway Steel Products, Inc., 304 Md. 67, 78, 497 A.2d 803 (1985). Here, the specialty care physicians treat patients largely as they see fit and are not subject to the control of the managed care corporation in the practice of medicine. Moreover, they are not paid wages in the ordinary sense; instead, they receive the fees paid by their patients or by third-party payors, subject to a service fee deducted by the managed care company. Furthermore, while the managed care corporation provides management services for practitioners and markets physicians' services, it is not itself engaged in the practice of medicine. Therefore, in our view, the specialty care physicians are not employees of the managed care corporation and would not qualify for that exemption.⁵

⁴ (...continued) provide care on a contractual basis.

⁵ The statute also creates an exception for payments pursuant to a written agreement that places the physician at risk. 42 U.S.C. §1320a-7b(b)(F). Because the specialty care physicians do not accept payments (continued...)

The regulations also create a safe harbor for amounts paid under personal services and management contracts, including amounts paid to independent contractors. 42 C.F.R. §1001.952(d). To come within that safe harbor, the agreement must be set out in writing and signed by the parties, as is the case here. It must also specify the services to be provided, provide for a term of at least one year, and avoid the counseling or promotion of a business arrangement or other activity that violates any State or federal law. These requirements also would seem to be met. The regulation also requires, however, that if the agreement is for the provision of services on a periodic, sporadic, or part-time basis, the schedule of these intervals, their precise length, and the exact charge per interval must be set out. In addition, the aggregate compensation must be set in advance. The agreement in question would not appear to meet the last two requirements. Therefore, the safe harbor for payments for personal services would not be available.

As we pointed out earlier, the unavailability of a safe harbor does not, in itself, mean that a violation has occurred. Instead, while an imbalance between the value of the services and the amount paid for them would constitute remuneration, it still must be determined whether the remuneration was paid with the intent of inducing referrals. We cannot make that determination.

D. Application to Dual Employment Question

As you explain the facts, the PHO director controls referrals of PHO patients from primary care physicians at the hospital to specialty care physicians, whether inside or outside the PHO. Since the PHO operates by marketing itself to managed care plans, the plan will ordinarily be the payor. Thus, unless the PHO has contracted with a federal health care program covered by the anti-kickback law, the law would not apply.

The law would apply if there were a contract with a federal health care program, many of which have started to use managed care systems. Nevertheless, it would not appear from the facts that any remuneration between the managed care company and the

⁵ (...continued) on a capitated basis, however, this exception is most likely not available.

director is being paid in order to induce referrals, since the facts reflect that he has the same contract with the managed care company as do those specialty care physicians that are not in a position to make referrals from the PHO. The PHO (not the managed care company) does pay the director extra compensation over what it pays for his services as a specialty care physician, and that compensation is clearly paid for services that include the making, or approval, of referrals, as the making and approval of such referrals is a part of his job. But he is making referrals as an agent of the PHO, in a context in which it cannot increase costs to the health program, at least where the program is paying on a capitated basis.

It is our view that referrals within a managed care system, made by an employee of that system, would not ordinarily be found to violate the anti-kickback law, so long as the payments are not intended to induce referrals in a way that will increase utilization or costs, but instead operate consistently with federal laws that permit delivery of program services through the use of managed care organizations. See, 42 U.S.C. §1395mm. If, however, the PHO pays the director in a way that rewards him for referrals to specialty care physicians employed by the managed care company, the anti-kickback law would be violated.

IV

Federal Self-Referral Statute

A. Text, History, and Purpose

The federal self-referral statute, 42 U.S.C. §1395nn, prevents physicians from making referrals to entities with which they or their immediate family have a financial relationship. The term "financial relationship" is defined so broadly that "virtually all business arrangements would fall within its scope." Dechene, "Stark II" and State Self-Referral Restrictions, 29 J. Health and Hosp. L. 65 (1996).

The statute, enacted in 1989 as part of that year's Omnibus Budget Reconciliation Act, originally covered only clinical laboratory services and applied only to Medicare. Pub. L. No. 101-239, 103 Stat. 2106, 2236 ("Stark I"). Unlike the anti-kickback statute, the self-referral statute does not require proof that a violation was knowing or wilful. See 60 Fed. Reg. 41,914 (August 14, 1995).

Moreover, it does not require proof that the financial relationship was entered into in order to induce referrals. Kucera, *Hanlester Network v. Shalala: A Model Approach to the Medicare and Medicaid Kickback Problem*, 91 N.W. L. Rev. 413, 427-428 (1996). In 1993, the statute was extended to cover additional "designated services" and to apply to Medicaid. Pub. L. No. 103-66, 107 Stat. 312 ("Stark II"). Even after Stark II, however, the list of services still makes the self-referral statute somewhat narrower than the antikickback laws, as does the limitation to referral by physicians. The legislative history reflects that the statute was not intended to supersede state laws that are more restrictive. H. Conf. Rep. No. 103-213, at 818, *reprinted at* 1993 U.S.C.C.A.N. 1496, 1507.

Opponents of self-referral fear that it leads to unnecessary tests, creates a conflict between the patient's interests and the physician's own, and could adversely affect the health care market by squeezing out other facilities and wasting health care dollars. Comment, *The Physician as Entrepreneur: State and Federal Restrictions on Physician Joint Ventures*, 73 N.C.L. Rev. 293, 295 (1994). Supporters of self-referral say that it encourages competition and allows physicians, rather than non-physicians, to maintain control over the delivery of health care services. McDowell, *Physician Self-Referral Arrangements: Legitimate Business or Unethical "Entrepreneuralism,"* 15 Am. J. L. & Med.

⁶ The legislative history reflects that the statute was not intended to affect or supersede the anti-kickback laws. H. Conf. Rep. No. 101- 386 at 856, *reprinted in* 1989 U.S.C.C.A.N. 3018, 3459.

⁷ The "designated services" are: clinical laboratory services; physical therapy services; occupational therapy services; radiology services; radiation therapy services and supplies; durable medical equipment and supplies; parenteral and enteral nutrients, equipment and supplies; prosthetics, orthotics, and prosthetic devices and supplies; home health services; outpatient prescription drugs; and inpatient and outpatient hospital services. 42 U.S.C. §1395nn(h)(6).

⁸ The Inspector General concluded that these effects were most pronounced with clinical services, finding that physicians with ownership interests in laboratories ordered 45% more tests than physicians without ownership interests. Office of Inspector General, Report to Congress No. OA-12-88-01410, May 1989, *reprinted in* CCH Medicare and Medicaid Guide ¶37,838.

61 (1989). Some commentators feel that Stark II goes too far and actually eliminates practices that could save the system money and result in better delivery of services. Comment, Regulation of Physician Self-Referral Arrangements: Is Prohibition the Answer or Has Congress Operated on the Wrong Patient?, 30 San Diego L. Rev. 161 (1993). Commentators have also remarked that possibilities for fraud in what is permitted are not that much different than in what is prohibited. McDowell, Physician Self-Referral Arrangements: Legitimate Business or Unethical "Entrepreneuralism", 15 Am. J. L. & Med. 61 (1989).

A few reported cases mention the self-referral statute. *See, e.g., United States v. Columbia/HCA Healthcare Corp.,* 125 F.3d 899 (5th Cir. 1997). We have found no cases, however, that actually interpret this law.

B. Application to Purchase and Transfer Question

The facts reflect that the professional medical practice was purchased by the hospital "through its corporate affiliate." The nature of the affiliate and its relationship to the hospital are not clear. The regulations define "hospital" as "a separate legally organized operating entity plus any subsidiary, related, or other entities that perform services for the hospital's patients and for which the hospital bills." 42 C.F.R. §411.351. If the affiliate does not meet this definition, a compensation arrangement between it and the primary care physicians relating to the purchase of the practice might not bar referrals to the hospital, at least if the affiliate has no ownership interest in the hospital and the relationship between the hospital and the affiliate is not such that the physician would benefit indirectly from it. See 60 Fed. Reg. 41945 (August 14, 1995). Dechene, "Stark II" and State Self-Referral Restrictions, 29 J. of Health & Hosp. L. 65, 68-69 (1996) ("The foregoing comments suggest that an affiliate to a hospital may be able to purchase a practice using installments as long as the affiliate does not have any financial interest in any entity that provides designated health

⁹ This possible effect was noted by the Inspector General when making recommendations concerning self-referral in 1989. Office of Inspector General, Report to Congress No. OA-12-88-01410, May 1989.

services."). The remainder of the analysis in this subpart applies only if the purchase by the affiliate is attributable to the hospital.

The purchase of a physician practice by a hospital can constitute a financial relationship that could lead to a violation of the self-referral statute if referrals are made to the hospital for any of the designated services covered by the statute. The statute contains an exemption, however, for an "isolated financial transactions, such as a one-time sale of property." 42 U.S.C. §1395nn(e)(5). The statute provides that, to qualify as an isolated financial transaction, the amount of remuneration must be consistent with the fair market value and not be determined in a manner that takes into account the volume or value of any referrals. *Id*. In addition, the remuneration must be paid pursuant to an agreement that would be commercially reasonable even if no referrals were made. Id. Finally, the arrangement must meet any other requirements established by the Secretary of Health and Human Services. Id. The regulations for clinical services expressly recognize that this exemption can include the one-time sale of a practice but provide that there can be no additional transactions between the parties for six months after the isolated transaction, other than those covered by other exemptions. 42 C.F.R. §411.357(f). The regulations also provide that a transaction that involves long-term or installment payments is not an isolated transaction. 42 C.F.R. §411.351.

We cannot determine whether the exemption for isolated financial transactions would apply in this instance, because we do not know whether the purchase price for the practice was at fair market value or would be commercially reasonable even if no referrals were made; whether payment for the practice was made in a single payment or over time; and whether the parties were involved in any other transactions in the six months after the sale. Depending on how it was done, the retransfer of the practice to the managed care company might have constituted an additional transaction. Other transactions may have taken place as well. If the exemption for isolated transactions does not apply, any referrals by the primary care physicians to the hospital for designated services, which include inpatient and outpatient hospital services, would violate the self-referral law.

C. Application to Percentage Payment Question

The federal self-referral law applies when a physician makes referrals to an entity with which the physician has a financial interest. A financial interest can be either an investment interest or a compensation arrangement. A compensation arrangement is any arrangement involving remuneration between a physician or an immediate family member of the physician and an entity. 42 U.S.C. §1395nn(h)(1)(A). Thus, a compensation arrangement can exist whether it is the entity paying the physician or the physician paying the entity. "Remuneration" is defined broadly to include "any remuneration, directly or indirectly, overtly or covertly, in cash or in kind." 42 U.S.C. §1395nn(h)(1)(B).

In this case, a compensation arrangement clearly exists. The specialty care physicians pay the managed care company a percentage of their fees, while the managed care company provides in-kind services to the specialty care physicians. The existence of a compensation arrangement prevents the specialty care physicians from making referrals for covered services to the other physicians in the managed care association unless there is an applicable exemption. Referrals for services other than covered services, however, are not affected. Thus, referrals for many of the services ordinarily performed by primary care physicians would still be permissible.

As far as we are able to ascertain, referrals to the hospital itself would not violate the self-referral law. There is no compensation agreement with the hospital, only with the managed care company. Just as an ownership interest in an entity that is also owned in part by a hospital does not constitute an ownership interest in the hospital, it is our view that a compensation agreement with an entity that is partially owned by a hospital does not constitute a compensation agreement with the hospital unless the entity is a part of the hospital. See 60 Fed. Reg. 41956 (August 14, 1995). The basic rule for whether a subsidiary will be treated as a part of the hospital is whether it provides services to the hospital's patients for

¹⁰ It is our view that when managed care company collects fees and then passes them on to the specialty care physicians after deducting its own fee, the remuneration is not from the managed care company rather but from the patient or the third-party payor.

which the hospital charges. 42 C.F.R. §411.351. In this case, the facts do not reflect that the managed care company is providing services for which the hospital charges. Thus, the self-referral law would not bar referrals to the hospital based on any compensation arrangement with the managed care company.

It is our view that referrals to physicians who are a part of the managed care company constitute referrals to an entity. Furthermore, it seems clear that the specialty care physicians have a financial relationship with that entity. The law would be violated by referrals to the physicians who are a part of the managed care company, however, only if the referrals were for covered services and no exemption were available.

The self-referral law has a number of exemptions that are potentially applicable. One exemption, for example, 42 U.S.C. §1395nn(b)(3), applies to payments for services provided by certain organizations authorized to provide services on a prepaid basis under federal health programs and for services provided by a qualified health maintenance organization to its enrollees. This exemption covers not only services provided directly by the entity, but also those provided pursuant to contracts with the entity. 63 Fed. Reg. 1696, 1712 (January 9, 1998). This provision has not been interpreted to apply, however, to "hybrid" entities, like the managed care organization that use both fee-for-service and capitated billing, 63 Fed. Reg. 1697 (January 9, 1998), although physicians affiliated with these entities may continue to refer Medicaid and Medicare patients to them if the physicians' arrangements with the entity qualify under some other exemption, such as the personal services exemption. Id.

The statute also creates an exemption for referral between physicians in the same group practice. 42 U.S.C. §1395nn(b)(1). The legislative history of Stark II expressly recognizes that the definition of group practice does not address the issues raised by part-time or independent contractor arrangements between a traditional group practice and specialists. H. Conf. Rep. No. 103-213, at 816, reprinted in 1993 U.S.C.C.A.N 1496, 1505. The original regulations interpreted the term to include practices that have part-time or contractual physicians. The most recent version of the regulations, however, adopted January 9, 1998, excludes physicians who are independent contractors. 42 C.F.R. §411.351.

The change reflects the conclusion that many group practices would have difficulty meeting the statutory requirement that substantially all of the members' services be performed through the group if they had "to consider as members the many specialists with whom they contract to furnish services through the group practice on a part-time basis." 63 Fed. Reg. 1687 (January 9, 1998). In light of that change, it would appear that the specialty care physicians are not members of any group practice that might exist among the primary care physicians, and therefore the exemption for referrals within a group practice would not apply.

The statute exempts amounts paid pursuant to a bona fide employment relationship. 42 U.S.C. §1395nn(e)(2). The regulations provide that the existence of an employment relationship is to be determined by the common law rules governing that relationship. 42 C.F.R. §411.351. As discussed in Part III C above, with respect to the anti-kickback law, it is our view that the specialty care physicians are not employees of the managed care company.

The statute also provides an exemption for remuneration to a physician under a personal services contract. §1395nn(e)(3), and for payments by physicians to entities for items and services if the items and services are "furnished at a price that is consistent with fair market value." 42 U.S.C. §1395nn(e)(8). It could be questioned whether the services provided for the physicians by the managed care company constitute remuneration, where those services are provided with respect to patients that have a patient relationship with the managed care corporation and the services presumably further that relationship. Those services, however, are clearly seen as having value to the specialty care physicians, because they are charged a fee for them. Moreover, remuneration has been interpreted to include "any payment of cash, property or services, whether not either or both parties receive a net benefit." 63 Fed. Reg.1708 (January 9, 1998). Therefore, this transaction could be subject to analysis under the exception for remuneration to a physician under a personal services contract.

That exemption requires that the arrangement be set out in writing, be signed by the parties, and specify the services covered by the arrangement. These requirements are met here. It further requires that the agreement cover all the services to be provided by the physician to the entity, which also appears to be the case from

the facts available to us. The next requirement is that the services contracted for do not exceed those that are reasonable and necessary for the legitimate business purposes of the arrangement. In this case, the purposes of the arrangement are to make specialty health care services available to the patients of the primary care physicians, and the services contracted for would appear to be reasonable and necessary to the achievement of that aim. The term of the arrangement is greater than one year, as required by the statute. In addition, the services to be provided do not, to the best of our knowledge, involve the counseling or promotion of a business arrangement or other activity that violates any state or federal law.

The final requirement is that the compensation to be paid is set in advance, that it does not exceed fair market value, and that it is not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties. In this case, the method of payment, in the form of the provision of services, is set in advance, but the total value is not known in advance, as it will depend on the volume of services performed by the physician, and as such, reflects the business generated between the parties. The conference committee report on Stark II observes that the requirement that the compensation be paid in advance is not intended to prohibit arrangements under which entities pay physicians on a per service basis, as long as other requirements are satisfied. H. Conf. Rep. No. 103-213, at 814, reprinted in 1993 U.S.C.C.A.N. 1496, 1503-1504. remuneration in question here is not payment on a per-service basis, as the payments are made by the patients. Instead, the remuneration arises from services provided for the specialty care physicians by the managed care company. These payments are not for services provided by the specialty care physicians in any ordinary sense of the term, especially since the value of the services provided by the managed care company varies, depending upon the source of the referral and where the patient is seen. Thus, the financial relationship between the specialty care physicians and the managed care company would not appear to fall within this exemption.

Although the provision of services to the physicians in excess of the amount that the physicians are charged is technically remuneration, it seems more natural to analyze this arrangement under the exemption for payments by physicians to entities for items and services if the items and services are "furnished at a price that

is consistent with fair market value." 42 U.S.C. §1395nn(e)(8). This exemption could apply to payments to management services organizations, even where the payments are made on a percentage basis. Hastings, Fundamentals of Health Law 37 (1995) ("This kind of compensation arrangement is consistent with the work required by these arrangements; greater productivity by the physicians requires greater management resources and should lead to greater compensation. To remain eligible for the exception, the parties must insure that the arrangement will be consonant with the fair market value of management services at all levels of productivity."). The exemption will not protect an arrangement, however, that does not reflect fair market value. As we have said before, we cannot determine whether the payments reflect fair market value.

The final potentially applicable exemption covers office and equipment rental. 42 U.S.C. §1395nn(e)(1). This exemption has requirements that would appear to prevent its use in this circumstance. Specifically, it requires that the rental be set in advance, that it be consistent with fair market value, and that it not reflect the volume or value of referrals or other business generated between the parties. Because the percentage payment to the managed care company does reflect the volume of referrals, this exemption would not apply.

In conclusion, many referrals from the specialty care physicians to the primary care physicians would not be for covered services and therefore would not violate the self-referral law. Referrals that are for covered services might be permissible if remuneration between the parties is exempt as a payment by a physician for items and services.

D. Applicability to Dual Employment Question

The arrangement that you describe puts the medical director in the position of making referrals to an entity, the managed care company, with which he has a compensation arrangement. Again, if no federal programs are involved, there would be no violation. In addition, no violation would arise if none of the referrals were for covered services. If federal programs and covered services are involved, however, a violation would arise unless one of the statutory exemptions applies. The analysis on this issue would be the same as above for the specialty care physicians, because the

medical director has the same contract with the managed care company as do the other specialty care physicians.

V

Maryland Self-Referral Statute

A. Text, Purpose, and Construction

The Maryland self-referral statute, Title, 1, Subtitle 3 of the Health Occupations Article, prohibits health care practitioners from making referrals to a health care entity with which the practitioner or an immediate family member has a "compensation arrangement" or in which the practitioner or an immediate family member holds a beneficial interest. A compensation arrangement is defined as "any arrangement or system involving any remuneration between a health care practitioner or the immediate family member of the health care practitioner and a health care entity." HO §1-301(c)(1).

Enacted as Chapter 376 of the Laws of Maryland 1993, the Maryland statute is similar to the federal law, but covers all services, all payors, and all health care providers, thus making it somewhat broader. The exceptions also differ from those in the federal law. For example, no exemption is made for isolated financial transactions. The Maryland statute reflects the view that the prohibited arrangements, in the words of the bill's sponsor, "result in abuse, over-charging, and over-utilization." Testimony of Delegate Ronald A. Guns on House Bill 1280 of 1993. See generally 79 Opinions of the Attorney General 438 (1994).

No cases have been decided under the Maryland law. Nor have implementing regulations been adopted.

Our research has found only two cases interpreting comparable state self-referral restrictions. The first, a Michigan case, held that the Michigan statute bars investment by independent practitioners in a freestanding facility to which they refer patients or specimens, even if referral is not required by the agreement and, indeed, even if the agreement expressly prohibits a physician from directing or requiring use of that facility. *Indenbaum v. Board of Medicine*, 539 N.W.2d 574 (Mich. App. 1995) *cert. denied*, 563 N.W.2d 198 (Mich. 1997). The second, a Florida case, interprets an exception in

Florida law for referrals for services provided by a facility operated by a group practice if the services provided are provided only for patients of the group practice. *Agency for Health Care Admin. v. Wingo*, 697 So. 2d 1231 (Fla. App. 1997).

B. Application to Purchase and Transfer Questions

The State law, like the federal law, is intended to reach situations in which the payments for the purchase of the practice extend over a period of time or a continuing compensation arrangement exists between the purchasing entity and the selling physician in the form of an employment contract or an independent contractor relationship. The omission of an exemption for isolated transactions, in a statute that is clearly modeled on the federal provision, raises the question whether a transaction like the sale of a practice is intended to bar referrals from the selling physicians to the purchasing entity, even in the absence of a continuing relationship. Neither the statute itself nor the legislative history addresses this issue. Thus, the relationship between the state and federal law would indicate that the intent was to bar such referrals. As a result, assuming that the relationship between the affiliate and the hospital was such that a compensation arrangement with the affiliate would be treated as a compensation arrangement with the hospital, the purchase of the professional medical corporation by the affiliate would render all referrals by the primary care physicians to the hospital illegal under the Maryland self-referral statute.

C. Application to Percentage Payment Question

The Maryland self-referral statute, like the federal statute, exempts referrals within a group practice, HO §1-302(d)(2); compensation arrangements with bona fide employees, HO §1-301(c)(2)(ii); and compensation arrangements with independent contractors, HO §1-301(c)(2)(iii). The definition of the term "group practice" in the State law is similar to the definition in federal law and raises the same issues. The bona fide employment exemption would not apply because, as discussed in Part III B above, the specialty care physicians are not employees of the managed care company. The exemption for payment for services provided as an independent contractor applies if the arrangement is for identifiable services, the amount of remuneration is consistent with fair market value and does not take into account the value or volume of referrals

by the health care practitioner, and the compensation is provided in accordance with an agreement that would be commercially reasonable even if no referrals were made to the health care provider. The arrangement in question is for identifiable services and is not affected by the level of referrals made by the health care practitioner. We cannot determine, however, whether it is consistent with fair market value or is commercially reasonable even in the absence of referrals.

The Maryland self-referral statute also has an exemption for referrals by a physician when treating a member of a HMO, if the physician does not have a beneficial interest in the entity to which the referral is made. HO \$1-302(d)(1). Since the specialty care physicians do not have a beneficial interest in the managed care company, referrals of HMO patients to primary care physicians employed by the managed care company would not violate the statute.

D. Application to Dual Employment Question

The Maryland self-referral statute applies to all payors and to all services. Thus, it is more likely applicable than the federal law. Moreover, Maryland law does not expressly exempt referrals to organizations that are providing services under the subchapter pursuant to prepaid contracts, though it does exempt referrals of members of HMOs, which would include some of the same referrals. It is our view, however, that, as under federal law, the exemption for contracts with independent contractors exempt this contract, since the managed care contract is for identifiable services and does not reflect the value of referrals made from the PHO. Any violation that does exist would not seem to be exacerbated by service as director but would depend, as in the case of the other specialty care physicians, on whether the payments are found to reflect fair market value and to be commercially reasonable in the absence of referrals.

VI

Conclusion

In summary, our opinion is as follows: Payment for the physicians' practice by the affiliate of the hospital raises conflict of interest issues, but we are unable to answer the question whether any

laws are violated on the basis of the facts that are available. Determination of this issue would require more information about the nature of the affiliate that made the purchase, the method of payment, and the nature of any additional transactions between the parties. In addition, it would be necessary to determine whether the amount paid for the practice reflected fair market value and would be reasonable for a buyer who had no expectation of future referrals. The arrangement under which the managed care company provides services to the specialty care physicians in exchange for a percentage of fees collected also raises conflict of interest issues, but the issue of whether any laws were violated would require an analysis of the relationship between the fee and the value of the services provided. The dual agency of the PHO Director raises possible kickback issues that cannot be analyzed without knowing how he is compensated by the PHO for his services as director.

Our research raises two questions about the Maryland self-referral law that the General Assembly may wish to address. The first is whether the omission of an exemption for isolated transactions has the effect of forever barring referrals from a physician who, for example, sold a single piece of property to a hospital but who has no other beneficial interest or compensation arrangement. The second is whether the exemption for referrals of HMO enrollees should be expanded to cover referrals of Medicaid recipients enrolled in managed care organizations pursuant to §15-103(b) of the Health-General Article and to referrals of patients in similar federal programs.

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